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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/570,738

03/06/2006

Joshua E. Meadow

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04/02/2008

Intellectual Property Dept./Dewitt Ross & Stevens

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EXAMINER

WIEST, PHILIP R

ART UNIT

PAPER NUMBER

3761

MAIL DATE

DELIVERY MODE

04/02/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/570,738	Applicant(s) MEDOW ET AL.	
	Examiner Phil Wiest	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-71 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-71 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 March 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/6/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, 5, 6, 11-15, 17-25, 27-30, 33-45, 50, 51, 55-60, 62, 64, and 68-71 are rejected under 35 U.S.C. 102(b) as being anticipated by Drevet et al. (US 5,643,195).

3. With respect to Claims 1, 2, 22, 38, and 58, Drevet discloses a fluid shunt for regulating the flow of cerebrospinal fluid ("CSF"), said shunt comprising an inlet port, an outlet port, a fluid passageway between said inlet and outlet, and a valve 14 situated between the inlet and outlet. The valve defines an upstream side and a downstream side (6 and 13) of the fluid passageway. The device further comprises a piston having a piston face defined on the upstream side of the passageway and being displaceable to actuate the valve (see Abstract). The fluid bearing on the piston face will actuate the valve and allow fluid communication between the inlet and outlet ports. A portion of the piston face is defined by a deformable diagram 9. The deformable diaphragm is connected to a spring 17 such that the diaphragm and spring provide a biasing force to maintain the valve in a closed state unless a sufficient pressure differential is provided.

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4. With respect to Claim 5, 6, 11, and 33, 50, 51, and 64, the piston is displaceable along a piston travel axis, and fluid flowing through the valve between the upstream and downstream sides (6 and 13) flows substantially perpendicular to said axis. The piston further comprises a piston tail opposite the piston face, and the downstream side of the fluid passage opens onto the piston only at the intermediate length of the piston. The piston tail is opposite the piston face, and the upstream side of the fluid passage opens onto the piston tail (see Figure 1). When a sufficient pressure differential across the diaphragm is present, the diaphragm will displace the piston along the travel axis and open the valve.

5. With respect to Claim 12-15, 25, 27-30, 40, 42, 43, 45, 60, and 62, the deformable diaphragm 9 includes a fluid side 7 bounded by the upstream side 7 of the fluid passageway, and an opposite side isolated from the fluid passage. The diaphragm 9 is biased by a spring 17. The opposite side is isolated from both the upstream and downstream sides of the fluid passage by the diaphragm 9, and the pressure of the spring 17 is capable of being adjusted by means of a screw 18 (see Figure 1). When a sufficient pressure differential across the diaphragm is present, the diaphragm will displace the piston along the travel axis and open the valve.

6. With respect to Claims 17, 23, and 24, 39, 44, and 59, the piston, diaphragm 9, and spring 17 are disposed adjacent the upstream chamber. Therefore, the position of the piston is independent of and isolated from the pressure in the downstream side of the fluid passage.

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7. With respect to Claims 18, 20, 21, 34-36, 55, 56, and 68-70, the device is designed to drain CSF from the cranium to a resorption site, such that the peritoneum (Column 1, Lines 5-17).

8. With respect to Claim 19, 37, 57, and 71, the outlet portion 4 has an extended flexible catheter 5 extending therefrom.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 3, 4, 16, 46-49, 61, and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Drevet in view of Drake et al. (US 5,192,265). Drevet discloses a flow-regulating CSF shunt substantially as claimed (see rejection above), but does not specifically disclose that the diaphragm comprises a fluid side in contact with the upstream chamber and a gas side, opposite the fluid side, bounded by a regulatable gas chamber. Drake discloses an adjustable CSF shunt comprising a fluid fluid passageway 5 surrounded by a pair of flexible walls (i.e. diaphragms). A gas chamber 9 is disposed on the opposite side of the flexible sheets from the fluid passageway, such that pressure is applied to the diaphragms to form a valve (Figure 1). When a low pressure differential exists between the inlet and the outlet, the valve is closed. When a pressure differential between the inlet port 7 and outlet port 8 is present, however, the

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diaphragms will deform, allowing fluid to pass through the fluid passageway.

Furthermore, Drake discloses that the gas pressure in the gas chamber 9 may be manually adjusted by moving a ball 14 through the gas pressure control means 10 (Column 3, Lines 34-44). The use of a gas source therefore allows a pressure to be applied to the opposite side of the diaphragm, thus eliminating the need for a spring member to apply pressure to the diaphragm. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the flow control device of Drevet with the use of a gas source to apply pressure to the opposite side of the diaphragm in order to provide a well known, alternate means for controlling the pressure differential between the inlet and outlet of a CSF shunt.

11. Claims 7-10, 26, 31, 32, 52-54, and 65-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Drevet in view of Marion (US 4,673,384). Drevet discloses the device substantially as claimed (see rejection above), but does not specifically disclose that the valve is formed as a cutout from the piston. Marion discloses a CSF shunt comprising a flow control valve therein. The valve is formed as a cutout (13, 14, 15) (i.e. a "mask") from a piston element 12, wherein the valve is opened and closed by aligning and unaligning the cutout with the drain port, thereby establishing fluid communication. Furthermore, the valve may be calibrated for any desired closing pressure for implantation (see Abstract). Valves that have cutouts through which fluid is permitted to flow are extremely common in the art of bodily fluid flow control. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to

modify the CSF shunt of Drevet with the cut-out-type flow control valve of Marion in order to provide a well-known, alternate means for controlling flow through the valve and regulating pressure across the shunt.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phil Wiest whose telephone number is (571)272-3235. The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Phil Wiest/
Examiner, Art Unit 3761

/Tatyana Zalukaeva/
Supervisory Patent Examiner, Art Unit 3761